

### Remarks

This paper is being filed along with a Request for Continued Examination under 37 C.F.R. 1.114.

Claims 12, 14, 15 and 33-37 are pending in the application. Claims 14 and 15 have been amended. New claims 38-40 have been added. Support for amended claim 14 is found, for example, in Example 1 of the specification. Support for new claim 38 is found on pg. 18, para. [0065]. Support for new claims 39 and 40 is found on pg. 13, para. [0050] of the specification and in originally-filed claim 12. No new matter has been added.

In view of the above changes and the following remarks, the Applicants respectfully request reconsideration of the claims.

### Response to the Claim Objections

Claims 12, 14, 15 and 33-37 are objected to for reciting "CB8+T." The term "CB8+T" has been deleted from claim 14, and has been changed to "CD8+T" in claim 15. These changes should obviate the objections to claims 12, 14, 15 and 33-37.

### Response to the section 102(b) rejection

Claims 12, 14, 15 and 33-37 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Grovit-Ferbas et al. The Applicants respectfully traverse the rejection.

To anticipate a claim, a reference must disclose, either expressly or inherently, every feature of the rejected claim. Here, claim 14 has been amended to specify that the HIV used in the claimed composition is *non*-recombinant. Grovit-Ferbas et al. disclose a dendritic cell which contains heat-inactivated HIV<sub>sx</sub>. HIV<sub>sx</sub> is a recombinant virus; see Grovit-Ferbas et al., pg. 5803, 2<sup>nd</sup> col. in the "Results" section, which states "[t]hese studies use the R5-tropic virus HIV<sub>sx</sub>, which contains the HIV<sub>JRFL</sub> envelope in an HIV<sub>NL4-3</sub> backbone."

Dependent claim 12 and new dependent claims 39 and 40 also specify that the inactivated HIV used to prepare the claimed composition is an autologous HIV. Grovit-Ferbas et al. did not use an autologous HIV to prepare their vaccine, but rather used HIV<sub>sx</sub>, which is a recombinant virus.

Claims 36 and 37 are directed to compositions in which the non-recombinant HIV is chemically inactivated, and new claim 38 specifies that the non-recombinant HIV is non-

thermally inactivated. Grovit-Ferbas et al. discloses a dendritic cell which contains heat-inactivated HIVsx. On pg. 3 of the Office Action, the Examiner notes that Grovit-Ferbas et al. discusses chemical inactivation of HIV. However, Grovit-Ferbas et al. discusses chemical inactivation of HIV in an experiment which is different from the experiment in which dendritic cells are exposed to heat-inactivated HIVsx. It is well settled that "an anticipation is not established if in reading a claim on something disclosed in a reference it is necessary to pick, choose and combine various portions of the disclosure not directly related to each other by the teachings of the reference." *Ex parte Beuther*, 71 USPQ2d 1313, 1316 (Bd. Pat. App. & Int. 2003) (citing *In re Arkley*, 172 USPQ 524, 526 (CCPA 1972)).

Thus, Grovit-Ferbas et al. does not disclose every element, either expressly or inherently, of claim 14 or its dependent claims 12, 14, 15 and 33-37, and new dependent claims 38-42. The Applicants therefore request that the 35 U.S.C. § 102(b) rejection be withdrawn.

The Claims are Non-obvious Over Grovit-Ferbas et al.

Claims 12, 14, 15 and 33-37, and new claims 38-40 are also non-obvious over Grovit-Ferbas et al.

To render a claim obvious, a reference must provide one skilled in the art with the suggestion to make the claimed invention, and with a reasonable expectation that the invention can be successfully made. Here, the claims are directed to composition comprising an antigen presenting cell pulsed with an inactivated non-recombinant human immunodeficiency virus (HIV), wherein the composition expands expression of virus-specific CD8+T cells.

Grovit-Ferbas et al. disclose a dendritic cell which contains heat-inactivated *recombinant* HIVsx. This dendritic cell was able to induce a cell-mediated recall response *in vitro*, as measured by the capacity to induce gamma interferon production in the PBMC isolated from three HIV patients, none of whom had a detectable viral load. No data is presented in Grovit-Ferbas et al. which shows that the dendritic cell of Grovit-Ferbas et al. expanded CB8+T cells, or was capable of inducing the CB8+T cells to kill HIV-infected cells. In fact, according to Grovit-Ferbas et al., pg. 5808, 2<sup>nd</sup> column (emphasis added):

Although it is not clear which cell subset produced IFN- $\gamma$  in response to our vaccine preparation, it is likely that the cytokine was secreted by **CD4** cells, since the DC were given an exogenous (antigen) for processing.

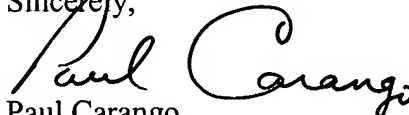
The compositions of claims 12, 14-15 and 33-37 and new claims 38-40 expand expression of virus-specific CD8+T cells. At best, the dendritic cells of Grovit-Ferbas et al., which contain *recombinant* HIV, elicit IFN- $\gamma$  production from CD4 cells. There is no evidence that the Grovit-Ferbas et al. dendritic cells can expand CB8+T cells. Indeed, Grovit-Ferbas et al. teaches that dendritic cells containing recombinant HIVsx elicit a CD4 cell response. Also, there is no suggestion in Grovit-Ferbas et al. to load dendritic cells with other HIV strains in order to achieve a different response.

Grovit-Ferbas et al. therefore does not suggest to one skilled in the art to prepare a composition comprising an antigen presenting cell pulsed with an inactivated non-recombinant human immunodeficiency virus (HIV), wherein the composition expands expression of virus-specific CD8+T cells, or that such a composition could be successfully made. Thus, Grovit-Ferbas et al. does not render claims 12, 14-15 and 33-37 and new claims 38-40 obvious.

#### Conclusion

In view of the foregoing, the Applicants respectfully submit the Application is now in condition for allowance, which is respectfully requested.

Sincerely,

A handwritten signature in black ink, appearing to read "Paul Carango". The signature is fluid and cursive, with the first name "Paul" and last name "Carango" clearly distinguishable.

Paul Carango

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